

REMARKS

Upon entry of the foregoing amendments, claims 1 to 3, 5 to 8, and 14 to 17 will be pending in the present patent application. Claims 1 to 3, 5 to 7, and 14 to 17 have been amended, without prejudice. Claims 4, 18, and 19 have been canceled, without prejudice. Claims 9 to 13 and 20 to 22 have been withdrawn as being directed to non-elected subject matter. Also, claims 1 to 3, 5 to 7, and 14 to 17 have been amended to remove non-elected subject matter. It is respectfully submitted that such amendments are not for the purposes of patentability, whether to avoid prior art or otherwise and, thus, no prejudice should be attached to the non-elected subject matter. Applicants reserve the right to pursue patent protection in a timely filed divisional application directed to the non-elected subject matter. No new matter has been added.

The Office Action includes rejections under 35 U.S.C. §§ 102(e) and 103(a). In view of the foregoing amendments and the remarks to follow, Applicants request that these rejections be reconsidered and withdrawn.

Discussion of the Claim Objections

Claims 3, 14, 15, 16, and 19 have been objected to as allegedly containing certain informalities (Action at 7 to 8). The pending claims have also been objected to as containing non-elected subject matter (id. at 9). Applicants submit, however, that the foregoing amendments have rendered the objections moot. Accordingly, reconsideration and withdrawal of the objections are respectfully requested.

Discussion of the Rejections Under Section 112, First Paragraph

Claims 1 to 8 and 14 to 19 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled with regard to the full scope of the claims. It is alleged that

Applicants' claims are not enabled with respect to "the N-oxide derivatives, prodrug derivatives, protected derivatives, individual isomers and mixtures of isomers of the compounds of formulas (I) and (II) ... stereoisomers, tautomers and pharmaceutically acceptable salts of the compounds of the formula I and II" (id. at 9), and that it would require undue experimentation to for the artisan of ordinary skill to make such compounds, despite the high level of skill attributed to such artisan (id. at 11 to 12). Applicants traverse this rejection because one skilled in the art having read the present specification and claims would be able to make and use the *full scope* of present inventions without engaging in undue experimentation.

It is settled law that whenever the adequacy of enablement provided by an applicant's specification is challenged, the examiner has the initial burden of giving reasons, supported by the record as a whole, why the specification is not enabling. *In re Armbruster*, 185 U.S.P.Q. 152 (C.C.P.A. 1975). The enablement requirement of 35 U.S.C. §112 is satisfied if a disclosure contains sufficient information such that persons of skill in the art, having the disclosure before them, would be able to make and use the invention. The legal standard for enablement under §112 is whether one skilled in the art would be able to practice the invention without undue experimentation. *In re Wands*, 8 U.S.P.Q. 1400 (Fed. Cir. 1988). Any experimentation that may be required is not undue as long as it is of a routine nature. *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Pat. Off. Bd. App. 1986). As the Federal Circuit noted:

The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable to determination of how to practice a desired embodiment of the claimed invention.

PPG Indus., Inc. v. Guardian Indus. Corp., 37 U.S.P.Q.2d 1618, 1623 (Fed. Cir. 1996)
(quotation and citation omitted).

Significantly, the Action fails to provide any facts indicating a reason to doubt that Applicants' disclosure would enable those skilled in the art to practice the claimed invention. The Action appears to rely on the fact that the specification provides no examples of the preparation of the disputed derivatives or isomers (Action at 11). Significantly, however, there is no legal requirement that Applicants exemplify every derivative or isomer that falls within the scope of the claims. Rather, all that is required is that one skilled in the art be able to practice the claimed invention, in view of the level of knowledge and skill in the art, without undue experimentation.

For example, the Action asserts that those skilled in the art would need to engage in undue experimentation to make the N-oxide derivatives, prodrug derivatives, protected derivatives, individual isomers and mixtures of isomers of the compounds of formulas (I) and (II) (Action at 9 to 10); however, there is *no reason* to believe that those of ordinary skill would have any difficulty in readily making such derivatives and isomers or that, if experimentation *were* required to make such derivatives and isomers, such experimentation would not be routine in nature. Indeed, the present specification provides considerable guidance in this regard. For example, the present specification clearly defines the disputed terms such as, for example, "isomers" (page 33 to 34), "N-oxide derivatives" (page 35), "prodrug" (page 36 to 37), and "protected derivatives" (page 37). Such definitions, in addition to being well known to those of ordinary skill in the art, are replete with literature references that are well-known in the art and are indeed supportive of enablement of the claimed derivatives and isomers.

Moreover, Applicants' specification provides an enabling disclosure sufficient to allow one of ordinary skill in the art to make each of the disputed derivatives and isomers. For example, Applicants' specification at page 50, lines 17 to 28, provides guidance on how to make the N-oxide derivatives of compounds of formula I. Applicants' specification at

page 50, line 29 to page 51, line 5, provides guidance on how to make the prodrug derivatives of compounds of formula I. Applicants' specification at page 51, lines 6 to 9, provides guidance on how to make the protected derivatives of compounds of formula I. Applicants' specification at page 51, lines 10 to 23, provides guidance on how to make the individual stereoisomers of compounds of formula I. Accordingly, any experimentation that may be required would *not* be undue in view of said teachings.¹ *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Pat. Off. Bd. App. 1986). Accordingly, Applicants respectfully request that the rejection for alleged lack of enablement be reconsidered and withdrawn.

**Discussion of the Rejection Under the
Judicially Created Doctrine of Obviousness-Type Double Patenting**

Claims 1 to 8 and 14 to 19 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 5 and 6 of commonly owned U.S. Patent No. 6,455,502. Applicants request that this rejection be deferred pending some identification of allowable subject matter, as it likely can be readily resolved (depending upon the subject matter ultimately allowed) through the filing of a suitable terminal disclaimer.

Discussion of the Rejection Under 35 U.S.C. § 102(e):

Claims 1 and 8 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,395,897 ("the 897 patent"). Applicants respectfully traverse this rejection because the 897 patent does not disclose each and every element of Applicants' claimed invention.

¹ Applicants note that the claims of U.S. Patent No. 6,455,502, which shares substantially the same disclosure as the present patent application, recite "and the N-oxide derivatives, prodrug derivatives, protected derivatives, individual isomers and mixtures of isomers; and the pharmaceutically acceptable salts thereof" of

In the first instance, Applicants do not concede that the 897 patent is prior art to the invention as now claimed, and Applicants hereby reserve the right to swear behind this patent if necessary. However, in view of the foregoing amendments, Applicants assert that the claimed invention is nevertheless patentably distinct over the disclosure of the 897 patent. In this regard, Applicants have amended the claims such that R⁴ no longer includes the group (C₆₋₁₂)aryl(C₀₋₆)alkyl. Thus, for at least this reason, Applicants submit respectfully that the 897 patent does not anticipate the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

Claims 1 and 8 have also been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,353,017 ("the 017 patent"). Applicants respectfully traverse this rejection because the 017 patent does not disclose each and every element of Applicants' claimed invention.

In the first instance, Applicants do not concede that the 017 patent is prior art to the invention as now claimed, and Applicants hereby reserve the right to swear behind this patent if necessary. However, in view of the foregoing amendments, Applicants assert that the claimed invention is nevertheless patentably distinct over the disclosure of the 017 patent. In this regard, Applicants have amended the claims such that R⁹ no longer includes the group "(C₁₋₆)alkyl" as an unsubstituted moiety as is present in Example 156 of the 017 patent. Applicants have also amended the present claims such that R⁹ no longer includes the group "(C₃₋₁₂)cycloalkyl(C₀₋₆)alkyl" as is present in Example 191 of the 017 patent. Thus, for at least these reasons, Applicants submit respectfully that the 017 patent does not anticipate the claimed invention. Accordingly, reconsideration and withdrawal of the rejection are requested respectfully.

the compounds recited therein. Accordingly, Applicants offer such evidence as further support that the full scope of the pending claims are indeed enabled, contrary to that asserted in the Action.

Discussion of the Rejection Under 35 U.S.C. § 103(a)

Claim 14 has been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the 897 patent. Applicants respectfully traverse this rejection as the Action has provided no evidence that one of ordinary skill in the art at the time of the present invention would have been motivated to modify the 897 patent in such a way as to arrive at Applicants' claimed invention as amended above.

The Action alleges that one skilled in the art would presented with the 897 patent at the time of the present invention would have been motivated towards Applicants' claimed invention because the 897 patent prepares "compounds which show preferences towards the variables R⁴ as C₁₋₆ alkyl substituted with cyano ..." (Action at 25 to 26). In the first instance, Applicants disagree respectfully that the 897 patent's disclosure of such compounds could render obvious the Applicants' claims. In any event, however, Applicants' claimed invention as amended above does not include the variables R⁴ as C₁₋₆ alkyl substituted with cyano. Such amendment amounts to even greater differences between Applicants' claim 14 and the prior art. Thus, there is no evidence of record as to why one of ordinary skill in the art at the time of Applicants' claimed invention and presented with the 897 patent would have been motivated to modify the teachings therein in such a way as to arrive at Applicants' claimed invention as amended above. Accordingly, reconsideration and withdrawal of the rejection in view of the 897 patent are requested respectfully.

Claims 14 to 16 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the 017 patent. Applicants respectfully traverse this rejection as the Action has provided no evidence that one of ordinary skill in the art at the time of the present invention would have been motivated to modify the 017 patent in such a way as to arrive at Applicants' claimed invention as amended above.

The Action alleges that one skilled in the art would presented with the 017 patent at the time of the present invention would have been motivated towards Applicants' claimed invention in view of the compounds disclosed in the 017 patent as Examples 156 and 191 (Action at 28 to 29). In the first instance, Applicants disagree respectfully that the 017 patent's disclosure of such compounds could render obvious the Applicants' claims. In any event, however, Applicants have amended claim 14 such that R⁹ no longer includes the group "(C₁₋₆)alkyl" as an unsubstituted moiety as is present in Example 156 of the 017 patent. Applicants have also amended the present claims such that R⁹ no longer includes the group "(C₃₋₁₂)cycloalkyl(C₀₋₆)alkyl" as is present in Example 191 of the 017 patent. Such amendments amount to even greater differences between Applicants' claims 14 to 17 and the prior art. Thus, there is no evidence of record as to why one of ordinary skill in the art at the time of Applicants' claimed invention and presented with the 017 patent would have been motivated to modify the teachings therein in such a way as to arrive at Applicants' claimed invention as amended above. Accordingly, reconsideration and withdrawal of the rejection in view of the 017 patent are requested respectfully.

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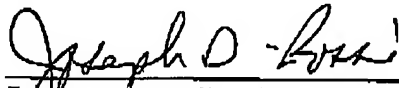
Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

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Joseph D. Rossi, Reg. No. 47,038
Attorney for Applicant

Aventis Pharmaceuticals Inc.
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, NJ 08807-0800
Telephone (908) 231-3410
Telefax (908) 231-2626